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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,947 | 11/26/2003 | Jorge Dubcovsky | 514112000320 | 4243 |

20872 7590 10/03/2006

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| EXAMINER |
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BAUM, STUART F

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------------|--|
| Office Action Summary | Application No. 10/723,947 | Applicant(s) DUBCOVSKY ET AL. | |
| | Examiner Stuart F. Baum | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 7/25/2006 has been entered.
2. Claims 1-27 and 36-37 are pending.
3. Newly amended and submitted claims 36 and 37, respectively, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 36 has been amended to recite sequences, identified as SEQ ID NO:79, 82 and 85 and claim 37 has been newly added and is drawn to sequences identified as SEQ ID NO:88 and 91. The specification teaches SEQ ID NO:82 and 85 are cDNA sequences for ZCCT2 (pages 32-34), while Applicants originally examined claims are drawn to nucleic acid molecules encoding wheat or barley ZCCT1 proteins.

Applicant is reminded that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another, as are different proteins structurally distinct chemical compounds and unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434). This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the subject matter of claim 36 drawn to SEQ ID NO:79, 82 and 85 and claim 37 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1-27 and 36, including SEQ ID NO:75 are examined in the present office action.
5. Rejections and objections not set forth below are withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 1 is indefinite in the recitation “ZCCT1”. The sole designation of an amino acid sequence by “ZCCT1” is arbitrary and creates ambiguity in the claims. For example, the amino acid sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different amino acid sequence. If either event occurs, one’s ability to determine the metes and bounds of the claim

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would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Written Description

8. Claims 1-27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/5/2006. Applicant's arguments filed 7/25/2006 have been fully considered but they are not persuasive.

Applicants contend the specification provides a clear definition of wheat ZCCT1 protein and sequences encoding wheat and barley ZCCT1 are disclosed (page 8 of Remarks, bottom paragraph). Applicants contend several structures of nucleic acid and polypeptide sequences of ZCCT1 proteins are disclosed. Applicants contend they are clearly in possession of an isolated nucleic acid that encodes a barley or wheat ZCCT1 polypeptide (page 9 of Remarks, top paragraph).

The Office contends the specification defines ZCCT1 proteins as those proteins that retain ZCCT1 activity. The specification continues by stating ZCCT1 activity depends upon the intended use of the ZCCT1 protein (See page 25 of specification, top paragraph). For example, one activity of ZCCT1 protein may be to interfere with the endogenous ZCCT1 activity, which could include ZCCT1 DNA binding activity without repression. The Office contends Applicants have not disclosed a structure/function relationship that demonstrates they are in full possession

of the broadly claimed genus, based on their definition of ZCCT1 protein. Therefore, the written description requirement is not satisfied for the full scope of Applicants' claims.

Enablement

9. Claims 1-27 and 36 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 4/5/2006. Applicant's arguments filed 7/25/2006 have been fully considered but they are not persuasive.

Applicants contend that the specification teaches how to use the claimed sequences, and references pages 81-83 of the specification (page 9 of Remarks, bottom paragraph). Applicants assert, "In fact, all plants carrying the transgene flowered 3-5 weeks earlier compared to the 11 plants that were homozygous for the absence of the transgene" (*Ibid*). Applicants contend the specification teaches many of the techniques required to enable the invention (page 10 of Remarks, 1st full paragraph). Applicants contend that using a disclosed technique, one could confirm that all plants carrying the transgene flower earlier than control plants. Applicants contend that it would be merely routine for one of skill in the art to express a ZCCT1 protein in a wheat plant or a barley plant (*Ibid*).

The Office contends Applicants elected Group I, drawn to a nucleic acid encoding a ZCCT1 protein. Group II of the restriction requirement is drawn to inhibiting expression of ZCCT1. The Office contends Applicants' teachings on pages 81-83 of the specification disclose

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methods for inhibiting expression of ZCCT1 in a wheat plant, and therefore give enablement support for the invention of Group II. Said disclosure does not support U.S.C. § 112 1st paragraph enablement requirement for the elected invention of Group I. In addition, given the broad definition of a ZCCT1 protein or polypeptide, which defines a ZCCT1 for example, as any polypeptide that is able to interfere with the endogenous ZCCT1 activity (See page 25, top paragraph), and given Applicants' disclosure of only full length sequences of SEQ ID NO:75 and 79, one of skill in the art would not be apprised of polypeptides that inhibit ZCCT1 activity that can be used in the elected invention. Therefore, given in part, the state-of-the art, the unpredictability, and the breadth of the claims as recited in the previous office action mailed 4/5/2006, undue trial and error experimentation would be required by one of skill in the art to make and/or use the broadly claimed invention.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

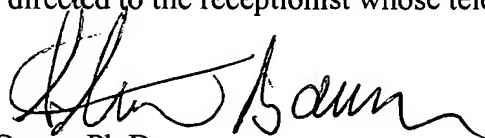
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Stuart F. Baum', is written over the printed name and title.

Stuart F. Baum Ph.D.
Primary Examiner
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September 27, 2006